The New York Needle Trial: The Politics of Public Health in the Age of AIDS

ABSTRACT

During the past 5 years, the exchange of sterile needles and syringes for dirty injecting equipment has gained increasing acceptance outside the United States as a potential means of reducing the transmission of the human immunodeficiency virus (HIV) among intravenous drug users. This article describes the controversy over attempts to establish a needle and syringe exchange scheme in New York City between 1985 and 1991. The response to a health crisis is used as an indicator of patterns of social and institutional practice. Advocates of needle exchanges had reached a stalemate with the promoters of law enforcement, and the strategic reformulation of the policy problem in terms of the research process seemed to offer a solution. The article discusses the practical limitations on designing and carrying out a controversial health promotion policy; the use (under constraint) of a restrictive research process to constitute—rather than simply to guide or monitor—public policy; and the potential ethical hazards of health professionals' seeking a polemical recourse to the clinical trial. The efforts to establish a needle exchange in New York thus illustrate more general problems for AIDS prevention. (*Am J Public Health.* 1991;81:1506–1517)

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Introduction

In January 1988 Stephen C. Joseph, MD, the New York City health commissioner, gained approval from the state health administration for a medical experiment, a controlled clinical trial. Usually the conduct of a clinical trial is respectfully left to the experts; rarely will its origins be announced on the front page of the *New York Times*, and its fortunes chronicled in subsequent editions. But this was no ordinary scientific trial. Law enforcement officials immediately called the experiment "unthinkable," and many of the city's minority leaders denounced it as "genocide." The trial was designed to recruit a limited number of drug addicts into a treatment group that would be permitted to trade in used needles and syringes for sterile equipment, and to compare their progress with that of a control group not given the same access to clean paraphernalia. From the beginning, New York's experimental needle exchange scheme—like so many other public health initiatives aimed at controlling HIV infection—was controversial, a focus for fear, frustration, and political maneuvering in the city. The troubled history of the needle exchange scheme illustrates the constraints on health promotion in a liberal American city overwhelmed by AIDS, drug addiction, and racial tension.

Although it has recently been argued that the development of AIDS policy offers "many examples of the triumph of the ethic of professionalism over the confused and conflicting claims of morality and ideology,"[3] the attempt to establish a needle exchange scheme in New York is not such an example. Here there was no broad agreement about policy, or who was in charge of it; no "reassertion of the authority of conventional medical and public health leaders" occurred in this case.[1] Instead, the attempt to explain and legitimate a needle exchange scheme revealed the limits of the health professionals' power in the city. Neither their institutional authority nor their access to the expertise and rhetoric of medical science ever allowed them to control the course of the debate.

This is only one incident in the response to AIDS in New York City, but it is a telling one. For the historian and for the social critic, AIDS serves, in Rosenberg's words, as "an extraordinarily useful sampling device" that illuminates "fundamental patterns of social value and institutional practice."[2] Weeks, too, has pointed out that conflicting social possibilities shape the ways in which we interpret illness and therefore organize the ways in which we respond. "What gives AIDS a particular power," he suggests, "is its ability to represent a host of fears, anxieties and problems in our current post-permissive society."[3] The methodological point has become commonplace, but rarely have its adherents provided us with the detailed and provocative social history one might ex-

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Editor's Note. See related editorial by Des Jarlais and Stepherson on page 1393.

pect. Indeed, for many of the more contemplative social analysts of AIDS, the epidemic has seemed principally an opportunity for historical analogy and sociological apriorism, an event apparently detached from the conditions of contemporary human suffering.[4]

My account of the social challenges of intravenous drug use and HIV infection in New York City focuses on the strategies that public health officials had to employ in order to legitimate a needle exchange. In Europe and Australia, the organized exchange of drug paraphernalia met with considerably less opposition from the start—with less ethnic hostility in particular.[5] Public health officials were able to "sell" such exchanges as unpleasant but probably effective mechanisms for harm reduction, and then to conduct further research on the relatively "user-friendly" programs. But in New York City a pilot needle exchange scheme, in order to have even a remote chance of acceptance, was packaged from the start as a controlled clinical trial, as a scientific experiment.

Health professionals—arguing that a rigorous scientific assessment of needle exchanges was still necessary—attempted to overcome contention and deflect responsibility for a controversial decision by resorting to the "objective" process of the clinical trial, so representing their actions as a scientific response to the crisis. Advocates of needle exchanges had reached a stalemate with the promoters of law enforcement, and the use of clinical science to structure public policy—a policy which in another political context would have been more pragmatic—seemed to offer a solution. That health professionals should seek a recourse, both scientific and polemical, to the clinical trial is not surprising. In this century, the controlled clinical trial has replaced anecdotal evidence as the irreproachable standard for evaluating and representing new medical interventions.[6,7] But the use of such a restrictive research process in part to secure a broad political consensus on public policy, as in this case, raises some difficult ethical questions—or, rather, it should have.

The conduct of a clinical trial requires constant vigilance to ensure that an effective treatment is not withheld from any untreated group during the course of the test. In order to establish and continue a clinical trial, the physician must be able to make an "intellectually honest admission that the best therapy is not known."[8] Fried has called this state of genuine uncertainty about effective therapy investigator "equipoise."[9] It is, of course, a condition often striven for, but rarely attained. The clinical investigator's failure to achieve equipoise has frequently appeared to present an obstacle to the ethical commencement or completion of a clinical trial. To overcome the ethical objection, Freedman has recently suggested the concept of "clinical equipoise."[10] According to this concept, the ethical requirements for a clinical trial are satisfied if there is genuine uncertainty within the expert medical community about the preferred intervention. But by late 1988, that part of the medical community whose expertise lay in the study of disease prevention and public health—the experts who would design and analyze any trial—could be reasonably sure that providing clean needles to intravenous drug users was one of the few interventions that might slow the transmission of the human immunodeficiency virus (HIV) and improve outreach education, without encouraging addiction. European and Australian studies (although no North American ones) offering evidence of these outcomes could be cited, as indeed they frequently were.

On the face of it, the rapidly improving scientific understanding of the subject that occurred during 1988 would make the maintenance of equipoise among the investigators, or in the relevant medical community, quite challenging. Yet at the same time, the only politically acceptable (and practically efficacious) way to distribute clean needles in New York City was by representing the intervention as a controlled clinical trial, and setting aside consideration of any potential ethical infractions. The efforts to establish the New York needle exchange trial thus illustrate some general problems for AIDS prevention: this commentary on recent events in New York examines the practical limitations on health promotion, the use (under constraint) of a restrictive research process to organize public policy, and the ethical hazards of health professionals' seeking a polemical recourse to the clinical trial.

Needle Exchanges for New York?

David Sencer, MD, then New York City's health commissioner, had first proposed the distribution of clean needles to drug users in September 1985. By refusing them access to clean needles, he said, "we are condemning large numbers of addicts to death from AIDS."[11] But the recommendation provoked vehement opposition. Law enforcement officials argued that addicts were not responsible enough to use clean needles to safeguard their own health: making needles freely available would only encourage young people to try drugs. The government would appear to officially sanction intravenous (IV) drug use. "How can cities ravaged by heroin," asked a *New York Times* editorial writer, "condone its use?"[11] A mayoral candidate, Carol Bellamy, attributed the plan to Mayor Koch, and denounced it as "one of the most hare-brained ideas I've heard from city government."[11]

Within a few days, Koch had rejected Dr Sencer's recommendation. All five of the city's district attorneys dismissed the idea, describing it as naive or unworkable. One of the plan's principal opponents, Sterling Johnson Jr, the special narcotics prosecutor in the Manhattan district attorney's office, wrote an impassioned letter to the mayor. "Drug addicts," he advised, "in the frenzied and desperate minutes before injecting a needle into their veins, could not care less about contamination." Experience had taught him that "slaves of addiction do not change their daily habits."[12] During a news conference at City Hall, Koch wryly observed that the idea was obviously one "whose time has not come and, based upon the response, will never come."[12]

By late 1985, over a million Americans had been exposed to HIV. The number of cases of AIDS was doubling each year. Almost 30% of the 4387 cases reported in New York since 1981 were IV drug users, and increasingly the experts feared that this group would transmit the virus to their spouses and children, passing the disease into the general community. Yet the prevention of HIV infection among drug users, who were mostly African American and Hispanic, had scarcely begun. All through the summer of 1985, city officials had been busy urging homosexuals to avoid the bathhouses. Responding to the growing public concern over the epidemic, Mayor Koch and Governor Cuomo were publicly reconsidering their opposition to the forced closure of the baths.[13,14] Meanwhile, angry parents in Queens were refusing to allow children with AIDS into their schools. The city's schools chancellor tried to reassure parents, promising them that all classrooms would have supplies of alcohol swabs and rubber gloves.[15] But no specific measures were taken to reduce the spread of the virus among drug users: there was, instead, a vague hope that an expansion of

drug treatment programs might take care of the problem.[16] Of the approximately 250 000 IV drug users in New York City, only 30 000 received treatment, and 1500 were on the waiting lists.

At the time, few models for a successful needle exchange scheme existed. The year before, however, the Amsterdam municipal health service, at the prompting of an association of drug users (the Junkies' Union), set up a needle and syringe exchange scheme in order to combat the spread of the hepatitis B virus. The clients of the exchange received one needle and syringe for each set they returned; the procedure was anonymous; and it was popular among the user community. Indeed, during 1985 over 100 000 needles and syringes were handed out. The exchange provided opportunities for educational outreach, counseling, and the distribution of condoms. Although clients were encouraged to stop injecting or to stabilize their habits with methadone maintenance, the approach generally was pragmatic rather than moralistic. "If it is impossible to cure an addict," wrote a promoter of the project, then "one should at least try to create a situation that greatly reduces the risk that the addict harms himself or his environment."[17]

The Mobilization of Professional Opinion

A consensus among health professionals began, slowly, to emerge. During 1986, news of the Amsterdam scheme, and a growing awareness of the dangers of HIV infection among drug users, prompted an international conference sponsored by the World Health Organization to conclude that "initiatives of this kind could have an important role to play in stopping the spread of HIV."[18] The Institute of Medicine of the National Academy of Sciences, in its report *Confronting AIDS*, discussed the Amsterdam project, and suggested that it was time "to begin experimenting with public policies to encourage the use of sterile needles and syringes by removing legal and administrative barriers to their possession and use."[19]

In May 1986, the New York State Health Department and the Milbank Memorial Fund sponsored an international conference in Manhattan to assess the impact of AIDS on public policy. Many of the delegates discussed the need for needle exchanges. Frederick Robins, MD, the former president of the Institute of Medicine, admitted it was a difficult issue, "but it seems to me that the time has come to seriously consider providing needles and syringes to drug users to avoid the necessity of using common instruments." His opinion was confirmed by James Curran, MD, the director of the AIDS program at the National Centers for Disease Control, who offered his support for a test program. "I would not discount anything in trying to combat this disease," he continued. "The problem we face is bigger than politics."[20]

Julian Gold, MD, a member of Australia's national AIDS task force, reported that needles and syringes were now freely available to drug addicts in Sydney, and drug addiction had not increased. But then Shellie Lengel, the director of public affairs at the US Public Health Service, discounted his claims. "We don't have any evidence it would help the problem," she said, "and our experts say the experience in other countries is not applicable to this country." David Axelrod, MD, the state commissioner of health, also opposed making needles and syringes more widely available, for he feared that this could lead to an increase in drug addiction. And this time Mayor Koch declared himself against the idea. "How can I support something that the police and law-enforcement leaders are totally against?"[20]

Andrew Moss, from the Department of Epidemiology at the University of California, San Francisco, reflected on the opposition to needle exchanges:

> You cannot legalize use here. It's politically impossible. It's been brought up in many jurisdictions, and uniformly gets squelched by mayors or attorney-generals or police chiefs. But you can do it in Europe, it's being done in Holland. . . We could go and look at them and find out how it works. If it's found to be successful, then we can come back and fill a huge gap in our own public policy discussions about this issue here.[21]

New Proposals for Needle Exchanges

During 1987, the city's new health commissioner, Dr Joseph, announced that the number of AIDS-related deaths among IV drug users was probably 1000 more than reported. He also estimated that, over the next year, nearly 800 babies infected with HIV would be born in the city, virtually all of them to mothers who were IV drug users. The Health Department predicted that by the end of 1991 there would be at least 40 000 AIDS cases in New York City and close to 30 000 deaths. Each year IV drug users would make a larger contribution to these figures.[22]

The *New York Times* had recently published a number of articles describing European needle exchange schemes. One of these reported that the Scottish Committee on HIV Infection had recommended that free clean needles and syringes be provided to IV drug users. After a crackdown on drug paraphernalia had forced Edinburgh's addicts to share dirty needles, the city had recorded the highest infection rate in Britain, mostly among drug users. In contrast, Glasgow, with no similar needle restrictions, had nearly twice as many drug users but far fewer AIDS cases. "The gravity of the problem," the Scottish committee declared, "is such that on balance the containment of the spread of the virus is a higher priority in management than the prevention of drug misuse."[23,24]

The same concern was expressed elsewhere in Europe, fueled by grim statistics. In Italy, more than half the 100 000 addicts were thought to be HIV positive; in France, the incidence of infection was probably 30%. Several countries were now prepared to try the Dutch model. Britain had decided to allow the exchange of needles and syringes in more than 10 cities. The Swiss government permitted pharmacies to sell syringes to anyone who wanted them. In France, drug users could exchange needles and syringes in pharmacies.[25]

Yet, as the *New York Times* pointed out in an editorial, little had been done in the United States to control HIV infection among drug users. In 1987, some 50% to 60% of New York's 200 000 heroin users were believed to be infected. And still there were long waits for methadone maintenance clinics and drug-free rehabilitation programs. In the "shooting galleries," meanwhile, addicts continued to rent and share dirty needles. Although dispensing clean needles might retard the transmission of HIV, law enforcement officers would resist on principle even "experiments" to test the possibility.[26]

But when Dr Joseph proposed such an experiment, his chief critics initially were the state health officials, who faulted the trial on technical grounds.[27] Dr Joseph had suggested that the city should dispense clean needles and syringes to several hundred addicts who were not HIV positive and who were waiting the many months it took to join a methadone maintenance program. An identical control group, addicts not given clean needles and

syringes, would also be monitored to assess behavioral changes and to measure relative rates of infection. This would be the nation's first trial of a needle exchange. But the proposed experiment did not satisfy the state's scientific requirements. State health officials doubted that the applicants for methadone programs were a truly representative sample of drug addicts; and the demonstration would, in any case, have to enroll several thousand addicts to provide scientifically valid results. Dr Joseph, contending that AIDS infection among drug users was a major threat to the city's health, promised he would come up with a revised trial.

Speaking a month later, Don C Des Jarlais, MD, of the New York State Division of Substance Abuse Services, told the Third International Conference on AIDS that the spread of HIV continued unabated among the nation's IV drug users. He recommended an expansion of drug abuse treatment, and a campaign to advise those who kept on using drugs how to inject safely.[28]

The least controversial policy, though, remained a "war on drugs." Citing a "state of emergency," city and state officials in June announced a new program that would provide treatment for another 3000 of New York's estimated 225 000 IV drug users.[29] The new clients would join the 30 000 people already enrolled at the city's 100 methadone clinics. But city officials, fearing neighborhood opposition, declined to give the proposed addresses of the new clinics, except to say that most would be located in parts of Harlem and Brooklyn that had high rates of addiction. Evidently, there was no policy that would not incite some opposition.

Forcing the Issue

The distribution of clean needles and syringes remained political anathema. In the midst of a crackdown on illicit drug use, there seemed no acceptable camouflage for any pragmatic scheme that made it safer to inject drugs. But in January 1988, the issue was forced. A community action group, the Association for Drug Abuse Prevention and Treatment (ADAPT), decided to defy state law and distribute free needles and syringes in the city. ADAPT was a private, nonprofit group, formed in 1980 to counsel addicts to stop using drugs and enter treatment. It was based in Brooklyn, and relied on donations and grants to support its 10 full-time staff members, most of whom were ex-users or sympathetic outreach workers. Unlike similar organizations in Amsterdam and Australia, current users were not active in its leadership.[30] The president of ADAPT, Yolanda Serrano, told the press that her association was prepared to face prosecution in order to "protect the public and save lives."

Dr Joseph praised the group's expertise and responsibility, but felt that he could not condone this illegal action. "It's regrettable," he said, "that the issue has come to a head in this way, when it's scientifically uncontrolled."[31] Sterling Johnson condemned the plan more vehemently. He speculated on whether it might be a prosecutable offense; perhaps there were even grounds for a criminal charge of homicide if an addict overdosed using one of the clean needles. But Ms Serrano thought the risks of the project were overstated. New York was one of 11 states restricting needles, yet it had the highest rate of drug abuse in the country. In any case, ADAPT intended to give clean needles only to those who already had dirty ones. It was too late, Ms Serrano declared, to engage in the research process. "Something has to be done now. Someone has to take the initiative to challenge the state in the name of public health."[31]

Dr Axelrod refused to comment on ADAPT's plans, but pointed out that the state was still considering a revised experimental needle exchange. Mayor Koch said that the law must be obeyed, although he would favor a limited experiment at some stage. "I have an open mind," Governor Cuomo was reported as saying, adding that the issue had been "tormenting me—it's very, very difficult."[32] But not everyone encountered the same difficulties. The Surgeon General, C Everett Koop, mentioned at the launching of an information brochure on AIDS that needle exchange schemes would be worth considering, even though they faced public resistance. "With a fatal epidemic that's spreading as this one is, you do anything in the world that you can do to stop it," he said. "And if providing free needles will stop it, that's fine."[33]

The Clinical Trial

Three days later, the Cuomo administration announced that it would let New York City conduct a revised clinical trial of needle and syringe distribution. State and city health officials stressed that the trial—the first time in the United States that a government would provide drug paraphernalia to addicts—was a scientific experiment and would be discontinued if it failed to retard the spread of AIDS. Dr Axelrod was confident that the new trial could produce scientifically valid results. He had previously opposed the idea of a needle exchange, arguing that addicts' behavior was so unpredictable that it would be impossible to monitor the program. But now he was prepared to approve Dr Joseph's revised proposal, if only for the purposes of research.[34,35]

The New York study initially would involve 400 IV drug users awaiting rehabilitation. At this stage, Dr Joseph proposed to draw addicts from targeted neighborhoods, rather than from the whole city, in order to make the experiment easier to manage. Each participant would be issued an identification card, with a photograph and fingerprint on it, and then would enter either the treatment group or the control group, depending on the site attended. All subjects were to receive counseling and general medical assistance. The proposal called for the randomization of the sites where the program was offered, rather than the randomization of individual subjects. Anyone who had enrolled in a control site would be free to withdraw and then reenroll at a treatment site, though this might mean traveling across town. No one had yet worked out how to entice the control group to return for regular monitoring; and no one could discern any obvious end point for the study. But since the average waiting time to enter a methadone maintenance program was 1 to 3 months (6 months to get into a drug-free program), the problem of finding an end point seemed unlikely to arise.

Law enforcement officers and drug rehabilitation experts soon found fault with the plan. The representatives of the law, and conservative politicians, found the very idea inimical, even in the guise of medical science. "It sends out the message that it is right to shoot drugs," declared Sterling Johnson. "It may be well meaning, but I think it is a very bad mistake."[36] The state assembly's Republican minority went on record unanimously as opposing any needle exchange scheme. The minority leader, Clarence Rappleyea, stated: "The notion of state-subsidized drug abuse is abhorrent."[37] The Catholic church also opposed the scheme: Cardinal O'Connor accused the city of "dragging down the standards of all society."[38]

Managers of drug treatment programs criticized both the design of the trial and its principle. Many, such as Dr Beny J. Primm, the director of the Addiction Research and Treatment Corporation,

feared that distributing needles would become a cheap substitute for rehabilitation. Robert Newman, MD, the president of Beth Israel Medical Center (the largest provider of methadone maintenance programs in the city), said he supported the idea of a needle exchange scheme but wondered how communities that resisted drug treatment centers would react to practicing addicts' appearing regularly to pick up their needles and syringes. Few of these experts could see how the experiment could come up with any meaningful scientific conclusion. According to Mitchell Rosenthal, MD, the president of Phoenix House (the chief provider of drug-free rehabilitation in New York), addicts were "the most disordered people in society" and were hardly likely to travel across Manhattan to register for an identification card.[39,40] This debate focused on the scientific legitimacy and the feasibility of the experiment: no one questioned the ethical aspects of not providing clean needles to a control group, or asked if a clinical trial was the best way to deal with a public health crisis.

The idea of distributing clean needles and syringes, one way or another, did have its nonmedical supporters, although they often were difficult to find. Thomas Morgan, a reporter with the *New York Times*, ventured into a shooting gallery to talk to some of them.[41] In an abandoned building near the Williamsburg Bridge in Brooklyn, he met a man who called himself Cano, "the man with the needles." A packet of 10 syringes, illegally acquired, cost him $4, he said, and he sold them to others for $2 each to support his heroin and cocaine habit. "People are buying them a lot because they don't want to share," he said. "People are afraid of AIDS." In the dim glow of the candles, Morgan also talked to a 32-year-old man called Willenski, who was fidgeting as he awaited his turn. "This talk about addicts liking to share needles is a lie," he said. "They don't want to give out free needles because they want us to die, and they see it as a good way to get rid of us."

Since 1984, ethnographic studies in New York City had suggested that addicts knew about AIDS and had taken steps to protect themselves. Drug users have an addiction and a culture that make risk reduction difficult: there is a deep mistrust of the outside world, a refusal to share needles can endanger personal relationships, and an addict keeping clean injection equipment runs the risk of arrest. Yet when 59 patients were interviewed at a Manhattan methadone maintenance clinic, 93% knew that sharing needles could spread the disease, 59% reported having made behavioral changes to avoid AIDS, 31% used clean needles more often, and 29% had reduced needle sharing.[42] Further studies indicated that Blacks were significantly more likely than other groups to report that they had decreased the sharing of works with other IV drug users: 48%, compared with 26% of Whites and 23% of Hispanics.[43] Des Jarlais and his colleagues observed, though, that "the extent of increased use of new needles would depend not only on the person's general intention to avoid sharing needles but also on market supply mechanisms for providing new needles at the appropriate times."[44] Outreach workers reported that the illicit market in New York for sterile needles had in fact expanded greatly, although perhaps not enough, since AIDS began. The threat of disease had even helped advertising. "Get the good needles, don't get the bad AIDS," one seller chanted.[44]

Through the summer of 1988, the debate continued. The increasing severity of the AIDS problem led more health professionals to push for a needle exchange scheme. Mervyn Silverman, MD, president of the American Foundation for AIDS Research, was reported in the *New York Times* in June as saying: "I never heard of anybody starting drugs because needles were available or stopping because they couldn't find a clean one."[45] With needle sharing now the leading means of HIV transmission in New York, Kathleen Oliver, the head of Outside-In, a private social service agency, thought that distributing clean needles was the sensible thing to do. By refusing to provide needles and syringes, "what you're really saying is these people are expendable, that you'd rather have them die of AIDS than give them needles."[45]

Dr Des Jarlais pointed out that in foreign cities where pragmatic needle exchanges had operated for many years now, no one could detect any rise in drug addiction. Recent evidence from Amsterdam, where 700 000 needles had been given out over the last year, implied that some addicts now injected less frequently, or had decided to enter treatment programs after counseling.[46,47] These findings were supported by preliminary studies in Sweden, England, Scotland, France, and Australia, countries where pragmatic distribution of drug injection equipment was permitted.[48–54] Yet it would probably take more years of observation to confirm that needle exchanges actually slowed the rate of seroconversion.

Some people felt that it was not worth waiting a few more years for further gains in scientific assurance.[55] Recent studies indicated that each year about 6% of IV drug users in New York City who formerly were not infected became HIV positive.[56] Before long, the prevalence of HIV infection might rival the 80% to 95% figures for hepatitis B infection found among drug users in New York City and San Francisco. Even in late 1987, a survey had shown that 1 of every 61 babies born in New York City carried antibodies to HIV, with most of the affected babies born in poorer neighborhoods.[36] With a public health disaster looming, needle exchange programs were now proposed in Boston, the District of Columbia, New Jersey, and San Francisco, as well as New York. San Francisco had been distributing bleach and telling addicts how to sterilize needles for over a year.[57] The Vancouver health authorities, convinced of "the success of needle exchange programs and, in particular, that such programs clearly did not encourage new drug users," had recently "sold" the idea of such a pragmatic scheme in their city.[58] In New York, though, the debate continued.

A Pilot Program Instead

In February, Dr Joseph had told Peter Kerr, a reporter from the *New York Times*: "We shouldn't delude ourselves. It is not a static situation. We don't have that much time."[36] But 10 months later, Joseph's proposed experiment still had not begun. As the months passed, even the tentative plans had been scaled down.

Predictably, no neighborhood wanted a needle exchange anywhere near it. John V Natoli, PhD, the principal of Public School 33 in Chelsea, was incensed when he heard that a needle exchange would soon open next door. "I have no objection to the program as an experiment," he said, "but as an educator, I don't see how you can place such a facility right next to a school."[59] He was worried that the area would become littered with used needles. Dr Joseph, though, pointed out that the Chelsea center already did HIV testing, so "hundreds if not thousands" of addicts passed the school every day. He believed the pilot program was under seige from critics "not because of any actual harm it could cause, but because it symbolizes the worst fears of its detractors."[59] But Mayor Koch stepped

in and cancelled the plans for neighborhood exchanges. Since Koch's decision suddenly meant that only one site was available, the proposed randomization of sites had to be abandoned just a few days before the start of the trial.[60] Now all subjects would have to travel across town to the health department's headquarters in lower Manhattan.

The "clinical trial" began on November 7, 1988, 3 years after Dr Sencer had first suggested the distribution of clean needles, and after 2 years of planning and redesign. The New York State Health Department's institutional review board had approved the new proposal, and the state health commissioner had finally promulgated the necessary regulations identifying the persons authorized to obtain and furnish hypodermic syringes (10 NYCRR § 80.134). But the trial was now called a "pilot study," and seemed less consequential than ever. Most likely, it would simply determine whether drug addicts could comply with the conditions of a clinical trial, although it might still provide some information on how effectively a needle exchange scheme slowed the spread of HIV infection. According to Dr Des Jarlais, for a large-scale trial to be feasible, the pilot study would have to attract enough volunteers, who would have to exchange their used needles regularly for clean ones and be prepared to enter drug treatment programs when vacancies occurred. Another important criterion of success was community support for the experiment.[61]

The number of IV drug users that could be enrolled was still limited to 400. To participate, addicts (18 years and older) had to register at the health department's headquarters in lower Manhattan, where they would be interviewed and examined by doctors, sign consent forms, and be tested for tuberculosis, sexually transmitted diseases, and HIV infection. These tests were to be repeated regularly throughout the trial. Only drug users who had applied to a drug rehabilitation program and been turned away because it was full were eligible for the study. When they came in to register they had to show a letter of referral from the program.[61,62]

Participants could exchange injection equipment between 10 AM and 3 PM Monday through Friday at the lone distribution site in downtown Manhattan, where they also received counseling and education. Each participant had an identification card with a photograph attached, to prevent others from getting access to the clean needles. Furthermore, the researchers planned to check the returned needles and syringes to make sure the blood in them was the same type as the participant's. If it wasn't, the participant would be warned, but no one had decided yet how many warnings were allowed before the refractory needle sharer had to be dropped from the study.

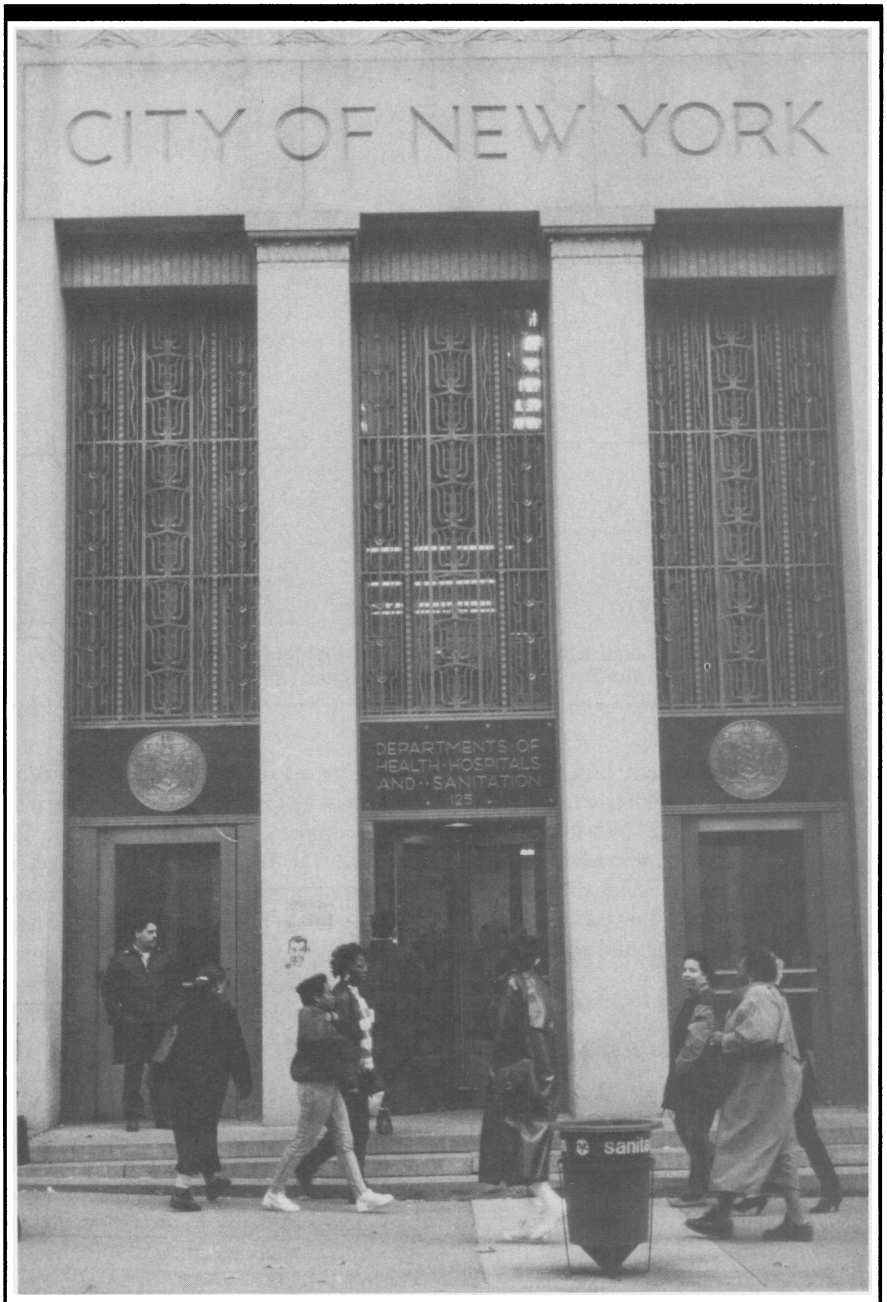

Photo of New York City Health Department Headquarters, site of needle exchange, by Marilynn K. Yee, *New York Times* Pictures. Reprinted with permission.

The initial proposal had included non-exchanging sites where members of a comparison group would also receive counseling, bleach kits, and basic medical assessment, but not injection equipment. This was to allow researchers to make statistical comparisons of behavioral changes and HIV infection rates between the "treated" and "untreated" groups.[62] But Koch's sudden decision to restrict the trial had thrown plans for a control group into confusion. Dr Des Jarlais suggested using a historical control, consisting of drug users that his group had been following for some years.[60] Eventually, though, a "comparison group" was found in the South Bronx. The needle exchange's staff gained access to a clinic, where they counseled the patients who injected drugs. Sixty-one patients decided to "pre-enroll" in the program; that is, they "completed all as-

Photo of ADAPT demonstration in in support of the distribution of clean needles by Chester Higgins, Jr, *New York Times* Pictures. Reprinted with permission.

pects of the enrollment procedure although they were unwilling to travel from the South Bronx to 125 Worth St to receive an ID card and hypodermic equipment."[62] This group became the comparison group that was followed for relative rates of needle sharing and seroconversion.

"Encouragement of Drug Abuse"

Only 2 people had enrolled by the end of the first day of the experiment. They first had to pass the barricades that police had erected in anticipation of protests against the scheme. In fact, by 10 AM only 20 demonstrators had gathered outside the health department, most of them from ADAPT, chanting slogans such as "Free needles save lives." The poor response from IV drug users did not surprise the demonstrators. Several of them pointed out that the single distribution center was inconvenient, with limited hours. Others observed that the study required addicts to identify themselves to a government agency.[61] Only eight applicants had shown up by the end of the week.

Meanwhile, criticism of the study became more vehement. Rarely, though, did critics bother any longer to challenge the scientific validity of the small, constrained trial, which even its promoters now seemed to assume was negligible. Instead, its opponents—including prosecutors, the police, Black and Hispanic politicians, and operators of drug treatment programs—expressed their concern that the government appeared to sanction IV drug use. The distribution of clean needles and syringes seemed to them a cynical, cheap solution to a drug problem that had brought not only AIDS but also crime, social breakdown, and other illnesses—such as tuberculosis—to the city's Black and Hispanic neighborhoods. A new sign was posted on lampposts in Harlem: "When will all the junkies die so the rest of us can go on living?"[63] The police commissioner, Benjamin Ward, told the *New York Times*: "As a black person, I have a particular sensitivity to doctors conducting experiments, and they too frequently seemed to be conducted against blacks."[64] The New York City Council voted overwhelmingly to approve a nonbinding resolution calling on the Koch administration to abandon the pilot needle exchange project. Enoch Williams, the chairman of the Council's Black and Hispanic caucus, argued that "the city is sending the wrong message when it distributes free needles to drug addicts while we are trying to convince our children to say no to drugs."[65] According to City Councilman Hilton B. Clark of Harlem, needle distribution was "genocide" and the program's architect, Dr Joseph, "should be arrested for murder and drug distribution."[66]

In response, Yolanda Serrano from ADAPT exclaimed: "They talk about genocide—this is the real genocide. People can survive addiction, but they can't survive AIDS."[66] Dr Joseph tried to calm things down and distance himself from the dispute: "People are taking positions based on opinions and assumptions without any data, and that's what we want to get."[66] But this appeal to the objectivity of medical research seemed no longer convincing enough to absolve health professionals from responsibility for their more controversial decisions.

During January, in another interview with the *New York Times*, Dr Joseph agreed that "it obviously has been a very tough row to hoe because of constraints placed on the program and the intensity of opposition to it."[67] After 2 months, only 56 addicts had enrolled, and only 76 needles had been dispensed. Health officials decided to alter the experiment so they could concentrate more on getting drug users into rehabilitation programs. Dr Joseph conceded that the number of addicts so far enrolled would be too few to draw any valid scientific conclusions.

For the past 5 months on a street corner in Tacoma, Wash, just a few steps from a shooting gallery, David Purchase had successfully handed out clean syringes in exchange for used ones. His volunteer efforts proved more popular than the New York experiment—13 000 needles had already been exchanged, even though fewer than 3000 IV drug users lived in Tacoma. Purchase, a 49-year-old drug counselor disabled from a motorbike accident, told reporters that needle exchanges elsewhere had been hampered by "ignorance, politics and moral fascism." He said that if dispensing clean needles and syringes turned out not to slow the spread of HIV infection, then he would just look foolish, but if those who blocked needle exchanges were wrong, "their children will be dead."[68] In Tacoma, Purchase had the support of the local police chief, who suspended enforcement of the law on possession of drug paraphernalia. But at the same time in Boston, a similar volunteer effort met a different fate, and the distributor was arrested. Another proposal to distribute clean needles, from a private social service agency in Portland, Ore, was being delayed by insurance problems.[69]

Uncertain Policies

In early 1989 the government response to AIDS in New York City was fragmented, contentious, and inadequately funded. Mayor Koch and other city officials blamed state agencies for cut-

ting reimbursements to AIDS patients, failing to expand hospitals, and stalling on clinics to treat drug addiction. State officials, in turn, attacked the city for neglecting public hospitals and shirking on drug treatment. Dr Axelrod, the state health commissioner, was confronted with extraordinary overcrowding in the hospitals and nursing homes he was responsible for. His city counterpart, Dr Joseph, had antagonized minority politicians with his promotion of a needle exchange program and had recently upset AIDS advocacy groups when he reduced the estimate of the number of New Yorkers infected with HIV.[70]

During that spring, a number of federal officials commented on the needle exchange experiment; initially, they supported it. The National Research Council, the research division of the National Academy of Sciences, produced a report on the national response to AIDS. To reduce the spread of HIV infection among IV drug users, the committee recommended an expansion of needle exchange programs.[71,72] Louis W. Sullivan, MD, President Bush's new Secretary of Health and Human Services, also endorsed needle exchange schemes. "I don't subscribe to the view that it condones drug abuse," he said. "It is an idea that certainly deserves some investigation to see if it does work."[73] But Representative Charles B. Rangel, a Manhattan Democrat who headed the Select Committee on Narcotics Abuse and Control, immediately condemned Dr Sullivan's comments, calling them "tragic, ill-advised and illegal." Needle exchange programs, he declared, "would keep addicts out of sight, out of mind, and sweep them under the rug instead of restoring their dignity and giving them drug-free lives."[74] Don Hamilton, a spokesman for William J. Bennett, the head of the Bush administration's anti-drug efforts, told the *New York Times* that needle exchange schemes were ineffective and, since they were likely to encourage drug abuse, also "pernicious."[75] Marlin Fitzwater, the president's spokesman, assured the press that "the President is opposed to the exchange of needles under any condition."[74] When asked about the apparent conflict, Campbell Gardett, a spokesman for Dr Sullivan, said, "We're in an in-between period when an awful lot has to be worked out."[76]

So the confusion over US needle exchange policy continued. In Europe and Australia the distribution of needles and syringes had been far less contentious. In April 1989, directors of AIDS prevention programs in Britain and the Netherlands told the House Energy and Commerce Subcommittee on Health and the Environment that providing clean needles and syringes to addicts had reduced needle sharing without increasing drug abuse. Allan Parry, who was in charge of 13 needle exchange programs in the Liverpool area, told the committee that since 1986 he had not found one case of HIV infection among the 1050 addicts that had received clean needles.[77] In Amsterdam, HIV infection among IV drug users had remained stabilized for 2 years, and new cases of hepatitis B had dropped 75%. Evidence from the only successful US exchange also suggested the project's effectiveness. According to Alfred Allen, MD, the Pierce County, Washington, health director, since David Purchase began distributing clean needles in Tacoma admissions to drug treatment programs had increased by one third. Local surveys indicated that 90% of addicts no longer shared needles. Purchase himself told the committee that he was convinced that protecting IV drug

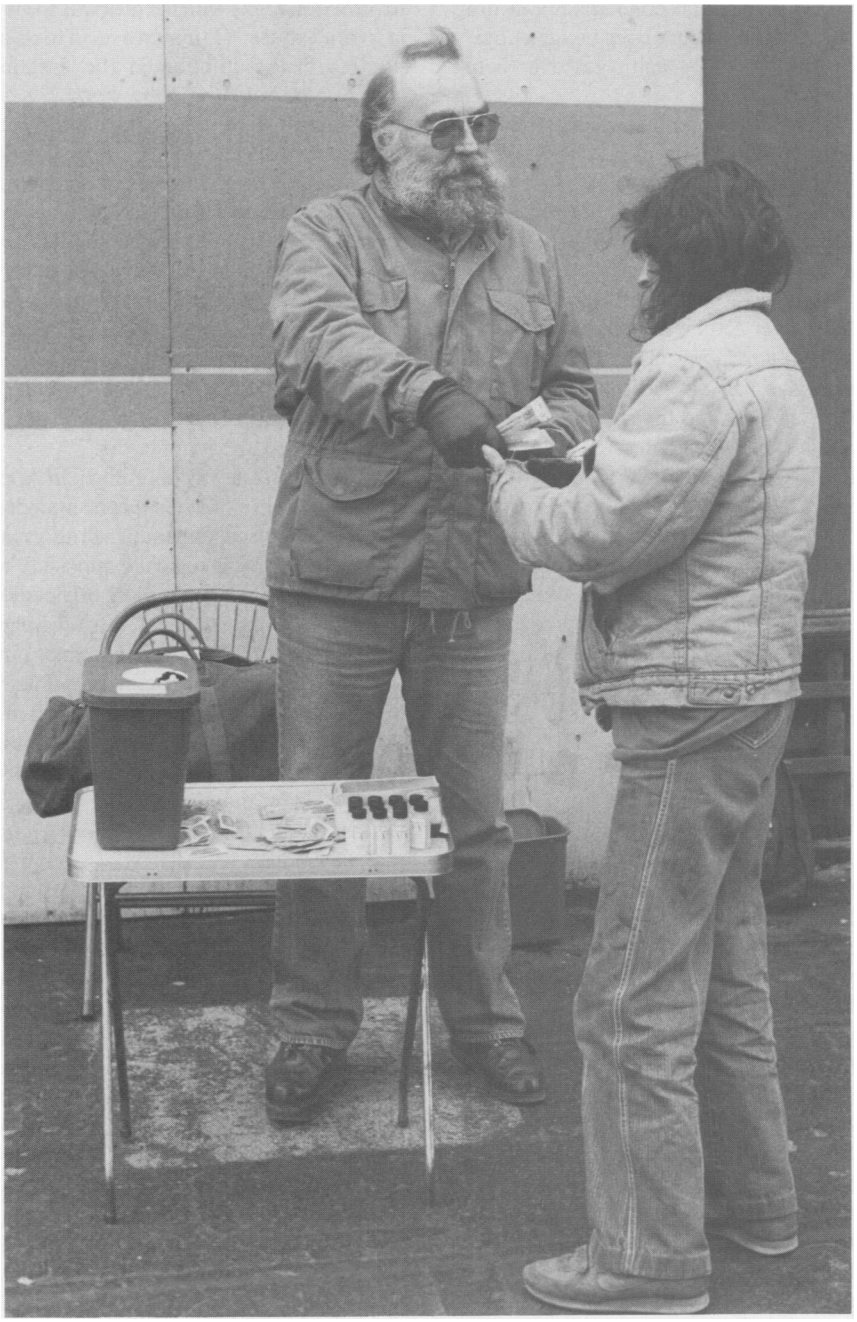

Photo of David Purchase, who operates the "user friendly" Tacoma needle exchange, by Doug Wilson, *New York Times* Pictures. Reprinted with permission.

users from a fatal disease was more important than moral concerns about drug abuse. "You can get over being stupid," he said, "but you can't get over being dead."[77]

But after 7 months, the carefully regulated New York needle exchange experiment had attracted only 160 participants. Dr Axelrod had recently permitted the program to accept addicts off the street, without letters of referral, but the other barriers to participation remained. Eventually, over 250 IV drug users enrolled in the program during its first 10 months, but there was still no sign that the data on these subjects and the comparison group would "begin a new less confrontational era of AIDS prevention policy."[62] Councilman Hilton Clark continued to argue that the program was a failure as an experiment, and the data collected showed nothing of any value. "People are not participating," he said. "We are going to call for a cessation of the program because it is still sending out the wrong message: using drugs is O.K."[78]

A Public Health Agenda?

The message that city health officials had hoped to send out was that the exchange scheme was a valuable scientific experiment in the prevention of HIV infection. Instead, the project was read as an endorsement of drug use. Never a popular suggestion, any hint of tolerance of addiction was, in the summer of 1989, politically unthinkable.

In September, George Bush warned that drugs were "sapping our strength as a nation" and announced a national drug control strategy that stressed law enforcement.[79,80] In his televised address from the Oval Office, he paid little attention to prevention efforts, or to the rehabilitation of addicts. Drug experts complained that neither Bush's program nor any existing state approach provided nearly enough clinics for addicts who wanted to break the habit. According to Salvatore di Menza, special assistant to the director of the National Institute on Drug Abuse, perhaps a million addicts wanted treatment that was simply not available.[81] Many of them languished on waiting lists for 8 months or more.[82] Many didn't bother even signing up.

When David Dinkins became mayor of New York, he confirmed the emphasis on the policing of drug use, appointing Nicholas Katzenbach, a former US Attorney General, to head a study group to recommend a strategy for fighting addiction.[83] Dinkins had always opposed the needle exchange experiment, arguing that to provide addicts with needles was to give in to drug abuse. "I think we need to go at fighting drug addiction in the first instance," he told the *New York Times*, "and I don't want to give people the paraphernalia to keep using drugs."[84] So when he announced the abandonment of the trial, in February 1990, it came as no surprise. Dr Joseph, though, who had been replaced as health commissioner by Woodrow A Myers, MD, expressed his disappointment with the decision. "Black leadership has consistently opposed it [the trial] and I think they made a big mistake," he said, "because some people who might have survived are going to die."[84]

At his first news conference, in April 1990, Dr Myers explained that he intended to concentrate on expanding drug treatment. He was "ideologically opposed" to the government distribution of needles and syringes, and could not, he said, imagine any evidence that would convince him that such schemes were worthwhile.[85] Myers also felt it was not the city's responsibility to teach addicts safer injection techniques, or to give them bleach to disinfect needles and syringes. In response, Dr Des Jarlais told the *New York Times* that he had reviewed needle exchange programs in Tacoma, Wash; Portland, Ore; Seattle, Wash; San Francisco, Calif; Great Britain; the Netherlands; Sweden; Australia; and Canada. He would be happy to discuss these studies with Myers. "They are really quite clear," he said. "Safe injection practices have not led to increased drug use, and have led to large reductions in AIDS risk behavior."[85] Yolanda Serrano, one of the few minority officials to have supported the idea of a needle exchange, was even more blunt. She pointed out that drug treatment was not readily available, and some addicts were unwilling or unable to enter rehabilitation programs. "What do we do, just let them die and take their families with them?"[85]

In May, a coalition of major AIDS organizations, including the Gay Men's Health Crisis and the American Foundation for AIDS Research (AmFAR), appealed to Dr Myers to change his opinion on the promotion of safe injection techniques. David Rogers, MD, head of the New York State AIDS Advisory Council and the Mayor's AIDS Task Force, claimed that eliminating prevention programs was "indefensible." Myer's actions had left him "absolutely bewildered."[86] Mathilde Krim, MD, cofounder of AmFAR, said she was in favor of "all these life-saving measures"—to be otherwise would be to label many drug users and their spouses and babies as "dispensable."[86]

Dr Myers also advocated withdrawing city funds from ADAPT's rather perfunctory bleach distribution efforts. The Black Leadership Commission on AIDS, a group of 65 doctors, lawyers, politicians, and business executives, supported his stand. They accused White public health officials of being too quick to endorse cheap ways of stopping AIDS, while failing to spend enough on drug treatment. Bleach distribution contained "a grave element of risk" to the African-American community, the commission said.[87] But according to Dr Krim, their statement was "contemptible, absurd and irrational." The debate was polarizing Blacks against Whites. "The majority of whites are in favor of preventing HIV transmission by any means," she said, but Blacks "are obsessed with the demand for treatment."[87]

By the end of the summer of 1990, no official needle and syringe exchange operated in New York City, and the informal bleach distribution was under threat.[88] While the more pragmatic exchange schemes in Europe and Australia were able to continue their expansion, the other tentative US efforts also seemed about to close down. The state of Washington's attorney general had warned that publicly financed programs to provide clean needles to addicts in Seattle and Tacoma were illegal.[89] Jon C. Parker, a former drug addict who was working on a master's degree in public health at Yale, had been arrested in Boston for distributing clean needles and syringes. Since 1987, he had given out over 50 000 needles, traveling a weekly circuit between Boston and Philadelphia.[90] Governor Dukakis and the Massachusetts legislature had repeatedly blocked requests from Boston's mayor for an official needle experiment.[90] And in a provision sponsored by Senator Jesse Helms, a Republican from North Carolina, Congress had voted to bar federal funds for needle exchanges, or even for the distribution of bleach.[90]

But in May 1990, against this trend, John C. Daniels, the first black mayor of New Haven, Conn, gained the city council's authorization for a local needle exchange scheme. He had argued that with 75% of the AIDS cases in New Haven linked to IV drug use, and over 4000 addicts in the city, making clean needles available would keep people alive until they could be helped. Officials hoped to

dispense 500 needle kits each week, and planned to expand the program to Hartford and Bridgeport by 1992. They had decided that the needle and syringe distribution would be more pragmatic than it had been in New York City. For a start, kits would be dispensed from a van traveling around the neighborhoods where addicts lived. The program had received enthusiastic support from New Haven's police chief, Nicholas Pastore. "The 1990's is calling for some new thinking in dealing with these issues," he said. "I like to see the Police Department's moving toward a social engineering role."[91] Alvin Novick, a professor of biology at Yale and chairman of the Mayor's Task Force on AIDS, told reporters: "This is not a political agenda: it's a public health agenda."[91,92]

Conclusion

In an interview in 1987 on the prospects for a needle exchange trial in New York, Dr Joseph had said: "The degree to which we can slow or stop the spread among intravenous drug abusers is the key to the future of the AIDS epidemic."[93] I have described here the history of one effort to curtail the spread of the virus among drug users.

My intention, however, is not to point out the "rational" course of action, or the "correct" public policy. There are lessons to be learned from this case, certainly, but they are not easily expressed in terms of right and wrong. I have tried, rather, to illustrate the contested meanings of health promotion and clinical research during the late 1980s in New York City—a diverse community facing an array of health crises and moral uncertainties. A number of groups—including public health officials, drug treatment experts, law enforcement officers, local community leaders, drug users, and federal, state, and city politicians—all had an interest in controlling the meaning of both the problem of HIV transmission among IV drug users and any intervention to curtail it. On a practical level, the various interpretations of the nature and severity of AIDS and illicit drug use determined each interested party's response to the needle exchange trial. The experimental program was regarded by health professionals as the most rational and scientific approach possible in the circumstances, but undoubtedly it was seen by other groups—ultimately more influential ones—as a symbolic endorsement of illegal drug use, the major perceived threat to the integrity of the community.

The failure of the New York needle exchange illustrates a social resistance to defining HIV infection as a technical problem, and reveals local limitations on the role of expert groups in the formation of controversial policy. Invoking the prestige of medical science is not always sufficient to compel acceptance of contested policies. Indeed, a deep mistrust of city health officials pervaded the dispute, making it difficult for them to avoid creating the impression that they were shielding political choices behind technical assessments. Although evidence from abroad suggested by early 1989 that the distribution of clean needles and syringes could reduce the sharing of drug paraphernalia without increasing addiction, this evidence clearly, in the end, was outweighed by the magnitude of the policy's symbolic affront to social order. Thus the control over the definition of the relevant issues had been wrested from the health professionals and, in the end, the explicit moral and political aspects of the problem proved paramount in defining society's response. As Nelkin and Hilgartner demonstrated in their study of a similar dispute in New York City, "symbolic and political issues have an important bearing on the acceptability of risk."[15]

In New York, the crisis of authority that Fox detected in the initial response to AIDS was never resolved.[94] The epidemic challenged a health system increasingly preoccupied with cost containment and the decentralization of authority. It was a fractured system, poorly prepared to devise and enforce a coordinated and convincing program to curtail the spread of the virus.[94-96] The intensity of disagreement over access to sterile injection equipment continues to illustrate how "the public rhetorical dramas of symbolic politics are a mechanism for coping with the fragmentation of political authority."[1] And at least in part, it confirms Porter's speculation that "the appalling slowness and ineptitude of the United States' response to AIDS arose out of the mixed blessings of the decentralized state and of City Hall caucus politics."[97]

It is not surprising that Mayor Dinkin's political decision should finally have ruled out a needle exchange in any guise in New York City. Again, the response to disease, as Rosenberg has observed, "lays bare every aspect of the culture in which it occurs."[98] Intravenous drug users in New York City were too unorganized and socially stigmatized to force government action, or to enter into negotiations over the appropriate policy response. They were the city's poor, mostly African American and Hispanic, an embarrassment to their families and communities—no one's constituency. In the past, drug treatment professionals had often claimed to speak for many addicts, but it was not necessarily in their interests to promote needle exchanges. African-American communities had been slow to mobilize against AIDS, and when they did, the leadership usually opposed the distribution of sterile injection equipment out of a concern that such a scheme would appear to endorse drug use and would substitute for rehabilitation. The churches that traditionally had taken the major role in mobilizing Black communities remained strongly opposed on moral grounds to any action that appeared to condone drug use. Only the members of ADAPT, a small group of outreach workers and past users, campaigned for access to sterile needles and syringes, but their contribution to policy negotiations remained marginal.[63]

The attempt to formulate public policy in terms of the research process—even though it failed—deserves close study, for there is a danger that political restrictions on access to care are simply replaced by research restrictions constructed on insecure scientific grounds. As soon as the provision of needle exchanges was structured as a scientific trial in New York, a recurrent anxiety emerged among the investigators: how to identify a control group that would give the experiment legitimacy. Political constraints on needle distribution were reiterated in scientific protocols that attempted to find an untreated comparison group to monitor, or simply limited the trial to the few prepared to negotiate a bureaucratic maze. The experiment, or the pilot study, was predicated on exclusion. This exclusion on scientific grounds, for research purposes, itself can be read as throwing doubt on the perceived rationality of needle exchange policy, as challenging an emerging international clinical consensus. In New York City—as in few cities abroad—public health officials maintained an agnosticism (or equipoise) on needle exchanges, and maintained it in practice long after they were able to quote studies indicating that the distribution of clean needles and syringes in a pragmatic fashion, with counseling, would be superior in therapeutic merit to the alternative of counseling alone, or perhaps counseling with bleach

distribution. This equipoise permitted them a polemical and scientific recourse to the clinical trial, and the local credibility they needed to exert an influence over events.

The tension between acceptance of pragmatic exchanges on the basis of existing knowledge, and the need to construct an acceptably limited experiment, is readily apparent. Even the city health department's report on the trial and the comparison group referred to needle exchange as "a promising—and necessary—intervention" in a "health crisis," and pointed out that "no empirical data" supported the principal arguments against such programs.[62] In a letter to Dr Axelrod in December 1989, Dr Joseph described needle exchanges as an "anti-HIV intervention already researched and adopted in many parts of the world," though not yet "field tested" in the United States.[99] Generally, the scientists involved argued that needle exchanges needed much more local controlled field testing (just as a vaccine might need more than one field trial), and that exchanges shouldn't yet be accepted as a standard of care[100]; yet in Europe and Australia such exchanges increasingly, in response to a crisis, were becoming so accepted. In the circumstances one might have expected at least more debate on the ethics of limiting "treatment" to a few, or making access to it difficult for a comparison group, for purposes of further US research of doubtful statistical power.[101] But then again, the interests of the population from which the trial drew its participants were not well represented.

But what if the configuring of policy as a restricted trial *had* been challenged on ethical grounds? Considering the balance of forces, such an attempt to bring AIDS prevention back into the middle of the political arena would most likely have resulted not in an expansion of access to clean needles, but in the abandonment of even the limited scheme—as eventually happened, although not from a squeamishness about restricting access for research purposes. But even if the choice was therefore between rigid political control over access to clean needles and a more flexible scientific control, one should bear in mind that our society has chosen to hold scientists to higher ethical standards in these matters than it demands of politicians. The issue, though, became so enmeshed in politics that no one can now say with certainty who was talking as a scientist and who as a politician: there was no room left for a relatively autonomous science. Nevertheless, when clinical science is used in an effort to attain a broader community consensus or political legitimacy for public policy—as much as to resolve a genuine clinical uncertainty—then one hopes scientists would be even more vigilant than usual in guarding against the possibility of refusing effective treatment to an untreated population, either in the trial or outside it altogether.

Since the rejection of the formulation of needle exchange policy as a research process, even fewer IV drug users in the United States now have authorized access to clean needles and syringes. (At the time of writing there are needle exchanges in New Haven, Conn; Hawaii; Portland, Ore; Seattle, Wash; and Boulder, Colo.) Yet in Europe and Australia, needle exchange schemes continue to expand in pragmatic ways. Thus a persisting irony of this story is that when the New York experiment ended, and the few local IV drug users ever permitted access to clean needles dispersed, the real international experiment on the effectiveness of needle exchange schemes had just begun: only now the majority of drug injectors in the United States will serve as the control group for the rest of the world. □

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